



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0725]

Abbreviated New Drug Application Submissions--Content and Format; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled “ANDA Submissions--Content and Format.”

This guidance is intended to assist applicants in preparing abbreviated new drug applications (ANDAs) for submission to FDA under the Federal Food, Drug and Cosmetic Act (the FD&C Act).

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring

that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2014-D-0725 for "ANDA Submissions--Content and Format." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document. FOR FURTHER INFORMATION CONTACT: Elizabeth Giaquinto Friedman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD, 20993, 240-402-7930.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "ANDA Submissions--Content and Format of Abbreviated New Drug Applications." This guidance is intended to assist applicants in preparing ANDAs for submission to FDA under section 505(j) of the FD&C Act (21 U.S.C. 355(j)). This guidance details the information that should be provided in each section of the common technical document format for human pharmaceutical product applications and identifies supporting guidance documents and recommendations issued by FDA to assist applicants in preparing their ANDA submission.

This guidance identifies the information an applicant should include to ensure that a complete, high-quality application is submitted to FDA. FDA has previously published guidance documents on the filing process, including the guidances for industry about refuse-to-accept standards and common, recurring deficiencies, which should be reviewed thoroughly prior to submission of an ANDA.

In the *Federal Register* of June 12, 2014 (79 FR 33758), FDA issued the draft guidance for industry "ANDA Submissions--Content and Format of Abbreviated New Drug Applications." FDA carefully considered the comments received on the draft guidance, and, where possible, has incorporated into the final guidance additional detailed discussion of our current thinking on the content and format of ANDAs submitted to FDA for review.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on the content and format of ANDA submissions. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 314 (including subpart C) related to the content and format of ANDAs submitted by applicants and approved by FDA is approved under OMB control number 0910-0001. Applicant submission of controlled correspondence related to generic drug development and FDA approval is approved under OMB control number 0910-0797.

The collection of information for Form FDA 356h (NDA and ANDA cover sheet) has been approved under OMB control number 0910-0338. The collection of information for Form FDA 3674 (application certification) has been approved under OMB control number 0910-0616. The collection of information for Form FDA 3794 (GDUFA cover sheet) has been approved under OMB control number 0910-0727. The collection of information for Form FDA 3454 and

Form FDA 3455 (clinical investigator financial interest) has been approved under control number 0910-0396.

The submission of petitions under 21 CFR part 10 (Administrative Practices and Procedures) has been approved under OMB control number 0910-0191. The collection information in 21 CFR part 11 (electronic records) has been approved under OMB control number 0910-0303. Information about the manufacture of the drug product under 21 CFR part 211 has been approved under OMB control number 0910-0139.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: September 19, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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